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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

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United States of America, <i>et al.</i> ,)	Civil Action No. 9:14-cv-00230-RMG
)	(Consolidated with 9:11-cv-1593-RMG and
Plaintiffs,)	9:15-cv-2458-RMG)
)	
<i>ex rel.</i> Scarlett Lutz, <i>et al.</i> ,)	
)	ORDER and OPINION
Plaintiffs-Relators,)	
)	
v.)	
)	
Berkeley Heartlab, Inc., <i>et al.</i> ,)	
)	
Defendants.)	
)	

This matter is before the Court on Defendant BlueWave Healthcare Consultants, Inc.’s (“BlueWave”) motion to dismiss¹ Relator/Plaintiff Chris Riedel’s first amended complaint (“FAC”) under Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), and 12(b)(6). (Dkt. No. 293.) For the reasons below, BlueWave’s motion to dismiss is granted in part and denied in part.

Background and Procedural Posture

BlueWave marketed lab tests for two laboratory companies, Health Diagnostic Laboratory, Inc. (“HDL”) and Singulex, Inc. (“Singulex”) from approximately 2010 through 2014. On December 30, 2011, Riedel filed a *qui tam* complaint in the District of Columbia, alleging that BlueWave, HDL, and Singulex violated the False Claims Act (“FCA”) through several fraudulent schemes (*e.g.*, billing for medically unnecessary tests and paying kickbacks to physicians facilitated by improper processing and handling fees, waivers of co-payments and

¹ BlueWave has styled its motion as a motion to dismiss and/or to strike under Rule 12(f). Defendant has not argued that any portions of Riedel’s FAC should be struck because they are “redundant, immaterial, impertinent, or scandalous.” Fed. R. Civ. R. 12(f). Not finding any grounds to strike, the Court has treated Defendant’s motion as a motion to dismiss.

deductibles, and Speakers Bureau fees). (Dkt. No. 91-2.) On August 7, 2015, the Government filed its Complaint In Intervention, alleging that BlueWave induced medically unnecessary testing and paid, or caused the payment of, unlawful kickbacks in the form of processing and handling fees to physicians. (Dkt. No. 75.) On December 21, 2015, BlueWave filed a motion to dismiss Riedel's first complaint. (Dkt. No. 139.) On March 28, 2016, this Court issued an Order finding that Riedel's allegations against BlueWave related to processing and handling fee kickbacks and medically unnecessary lab tests were barred by the first-to-file bar of the FCA. (Dkt. No. 268.) The Court dismissed Riedel's Complaint without prejudice for failure to plead fraud with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. Riedel filed his FAC to cure those deficiencies. The FAC alleges that BlueWave violated various provisions of the FCA, including

- (1) Presenting false claims in violation of 31 U.S.C. § 3729(a)(1)(A);
- (2) Making or using false records or statements material to payment or approval of false claims in violation of 31 U.S.C. § 3729(a)(1)(B);
- (3) Retention of proceeds to which not entitled in violation of 31 U.S.C. § 3729(a)(1)(G);
- and
- (4) Conspiracy to commit violations under 31 U.S.C. § 3729(a)(1)(C).

(Dkt. No. 286.) Riedel alleges that BlueWave committed these FCA violations through its participation in five illegal schemes:

- (1) Waiver of private insurance co-payments;
- (2) Waiver of private insurance deductible payments;
- (3) Payment of inflated packaging fees to physicians to induce referrals ("P&H fees");

(4) Payment of “Speaking Fees” to physicians who signed up to be in Defendants’ “Speakers Bureau”; and

(5) Systematic billing for medically unnecessary tests (“Unnecessary Tests”).

(*Id.*)

BlueWave argues in its motion to dismiss that (1) Riedel’s claims in connection with P&H Fees and Unnecessary Tests are barred by 31 U.S.C. § 3730(b)(5) (the “first-to-file” bar) and the law of the case; (2) Riedel does not have Article III standing to pursue any FCA claims against BlueWave on which the Government has intervened; and (3) Riedel’s FAC should be dismissed for failure to meet the pleading requirements of Rules 8, 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure. (Dkt. No. 293.)

Legal Standards

I. Motion to Dismiss for Failure to State a Claim – Rule 12(b)(6)

To survive a Rule 12(b)(6) motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 (2007)). Complaints that merely offer “labels and conclusions” or “a formulaic recitation of the elements of a cause of action” will not survive. *Twombly*, 550 U.S. at 555. A motion to dismiss under Rule 12(b)(6) “should not be granted unless it appears certain that the plaintiff can prove no set of facts which would support its claim and would entitle it to relief.” *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993).

“Facts that are ‘merely consistent with’ liability do not establish a plausible claim to relief.” *U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678). “A claim has facial plausibility when the plaintiff pleads factual content

that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 668. “In addition, although [the court] must view the facts alleged in the light most favorable to the plaintiff, [the court] will not accept ‘legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments.’” *Nathan*, 707 F.3d at 455 (quoting *Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012)).

II. Pleading Fraud with Particularity – Rule 9(b)

A complaint alleging fraud “must state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). However, “[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally.” *Id.* To meet this standard, the complaint must describe “the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.” *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999)). In other words, the complaint must describe the “who, what, when, where, and how of the alleged fraud.” *Id.* (quoting *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 384 (5th Cir. 2003) (internal quotation marks omitted)).

Finally, “[a] court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial pre-discovery evidence of those facts.” *Harrison*, 176 F.3d at 784. Rule 9(b) also requires a complaint to include “some indicia of reliability” to “support the allegation that an actual false claim was presented to the government.” *Nathan*, 707 F.3d at 457 (internal citation omitted). A complaint

provides the requisite the indicia of reliability where “specific allegations of the defendant’s fraudulent conduct necessarily [lead] to the plausible inference that false claims were presented to the government.” *Id.*

Discussion

I. First to File Bar

BlueWave argues in its motion to dismiss that Riedel’s allegations related to P&H fees and Unnecessary Tests are barred by 31 U.S.C. § 3730(b)(5) (the “first-to-file” bar) and the law of the case. This Court’s prior Order found that both schemes were barred by the first-to-file rule. (Dkt. No. 268 at 35.) Riedel confirmed that he does not seek reconsideration of this Court’s prior Order and has only included these schemes in his FCA to preserve his rights on appeal. (Dkt. No. 312 at 6-7.) Riedel’s claims in connection with the P&H fees and Unnecessary Tests are therefore dismissed.

II. Article III Standing for Government-Intervened Claims

The Government has intervened as to Riedel’s claims related to P&H fees, Unnecessary Tests, BlueWave’s commission agreements with HDL and Singulex, and a conspiracy to violate the FCA. BlueWave asserts that this Court has no jurisdiction over any of Riedel’s claims on which the Government has intervened because Riedel lacks Article III standing to pursue them. (Dkt. No. 293 at 10.) When filed, the Government’s Complaint In Intervention becomes the operative complaint as to all intervened claims. *U.S. ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 648–49 (S.D.N.Y. 2011) (“by automatic operation of the statute, the Government’s complaint in intervention becomes the operative complaint as to all claims in which the government has intervened”). If the Government intervenes, “it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing

the action,” but the person bringing the action, in this case Riedel, “has the right to continue as a party to the action”² 31 U.S.C. 3730(c)(1); *see United States v. Triple Canopy, Inc.*, 775 F.3d 628 (4th Cir. 2015), *judgment vacated on other grounds sub nom. Triple Canopy, Inc. v. U.S. ex rel. Badr*, 136 S. Ct. 2504 (2016).

III. Pleading Fraud with Particularity – Rule 9(b) and Rule 12(b)(6)

This Court previously dismissed the non-intervened claims in Riedel’s first complaint because Riedel did not plead fraud with particularity as required under Rule 9(b). For example, Riedel’s first complaint did not specify how Defendant BlueWave, as opposed to HDL or Singulex, violated the FCA. Instead, Riedel’s initial complaint often referred to the three Defendants collectively. Because BlueWave is a marketing company, not a testing laboratory or diagnostic company like HDL and Singulex, it was unclear which conduct Riedel’s first complaint attributed to BlueWave. This Court allowed Riedel to file a first amended complaint to attempt to cure these deficiencies.

BlueWave has now moved to dismiss Riedel’s FAC under Rules 8, 9(b), and 12(b)(6). Specifically, BlueWave argues that Riedel’s complaint fails to allege the following claims with particularity:

- (1) The Speakers Bureau kickback scheme;
- (2) The waiver of co-payments/deductibles kickback scheme;
- (3) Making or using false records or statements material to payment or approval of false claims under 31 U.S.C. § 3729(a)(1)(B);

² This right is subject to some limitations, for example, “Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.” 31 U.S.C. 3730(c)(2)(D). BlueWave has not alleged and this Court does not find that any of the limitations in 31 U.S.C. 3730(c)(2) apply.

(4) Retention of proceeds to which not entitled under 31 U.S.C. § 3729(a)(1)(G); and

(5) Conspiracy to commit violations under 31 U.S.C. § 3729(a)(1)(C).

(Dkt. No. 286.)

a. Violations of the Anti-Kickback Statute

Plaintiff has alleged that BlueWave violated the FCA through participation in two kickback schemes that violated the Anti-Kickback Statute (“AKS”): the Speakers Bureau kickback scheme and the waiver of co-payments/deductibles kickback scheme. This Court held in its prior Order that a violation of the AKS constitutes a violation of the False Claims Act. (Dkt. No. 268 at 8-10, n. 2-3.) Plaintiff must plead AKS violations with particularity under Rule 9(b). *See United States ex rel. Nunnally v. West Calcasieu Cameron Hosp.*, 519 F. App’x 890, 894 (5th Cir. 2013) (“elements of the AKS violation must also be pleaded with particularity under Rule 9(b), because they are brought as a FCA claim”) (citing *United States ex rel. Bennett v. Medtronic*, 747 F. Supp. 2d 745, 760, 783-85 (S.D. Tex. 2013)).

This Court dismissed Riedel’s initial complaint because it failed to plead fraud with particularity as required by Rule 9(b) with regard to BlueWave’s involvement in the two kickback schemes - it did not describe the who, what, when, where, and how of the alleged fraud. (Dkt. No. 268 at 21-23.) BlueWave argues now that although Riedel’s FAC “identifies physicians who purportedly received kickback payments from” both schemes, the FAC does not list enough specific pieces of information about the schemes to satisfy Rule 9(b) (*e.g.*, specific false claims, specific patients, specific dates or amounts paid, the number and type of tests ordered). BlueWave insists that although the FAC “contains details of how the scheme worked, those details do not cohere into representative examples of fraud.” (Dkt. No. 293 at 13-14);

United States ex rel. Kroening v. Forest Pharm., Inc., No. 12-366, 2016 WL 75066, at *8 (E.D. Wis. Jan. 6, 2016).

With regard to the co-payment and deductible waiver scheme, the FAC alleges that BlueWave's agreements with HDL and Singulex required the laboratories to agree not to charge patients for co-payments or deductibles. (Dkt. No. 286 ¶¶ 19, 22, 23, 30, 31.) BlueWave then leveraged the laboratories' no-balance billing practices to induce physician referrals by highlighting the practice in written pamphlets it gave to physicians. (Dkt. No. 286 at 32.) BlueWave quibbles that Riedel's FAC does not name specific claims and specific patient referrals from physicians who received kickbacks. The FAC actually does more – it identifies physicians and practices who were induced by BlueWave's promise of co-payment and deductible waivers to refer *all* of their patients to BlueWave's laboratory clients. (*Id.* ¶¶ 49-61.) The FAC indicates that BlueWave used co-payment and deductible waivers to induce physicians to refer business in exchange for kickbacks, that HDL and Singulex billed Medicare for patients so referred, and that HDL and Singulex paid BlueWave commissions in excess of \$218 million in connection with those referrals. The Riedel FAC has described the who, what, where, when, and how of the fraudulent scheme in enough detail to give BlueWave adequate notice of Plaintiff's allegations to prepare a defense at trial. There is no need for the Riedel FAC to distinguish between legal and illegal referrals as he has alleged that all referrals from some physicians and practices were tainted by the improper promise of co-payment and deductible waivers. Determining whether some of the lab test referrals may have been legitimate is a task for discovery.

Likewise, with regard to the Speakers Bureau kickback scheme, the FAC alleges that BlueWave originated the idea for this scheme, that BlueWave sales representatives contacted

physicians to arrange their speaking engagements and payment, identifies the physicians involved in the Speakers Bureau and the amounts they were paid, alleges that the payments were made to induce additional referrals (and were not fair market value compensation for speaking), and alleges that patients were actually referred to HDL and/or Singulex as a result. (Dkt. No. 286 ¶¶ 20, 24, 42, 45, 46, 47.) These allegations are sufficient to survive a motion to dismiss under Rule 9(b) and Rule 12(b)(6).

Finally, BlueWave argues that the Riedel FAC fails to allege the requisite scienter for the AKS/FCA claims because it did not specifically allege “scienter of any BlueWave officer or employee involved in the actual presentation of any false claim.” (Dkt. No. 293 at 16.) The FAC does allege that specific individuals at BlueWave, including Mr. Dent and Mr. Johnson (its founders), understood that the conduct BlueWave was engaged in was illegal. (Dkt. No. 286 ¶¶ 22, 23, 25, 72.) To *prove* a violation of the AKS at trial, Riedel will need to show that Defendants acted with a purpose to commit a wrongful act, but it need only allege a purpose to commit a wrongful act to survive a 12(b)(6) motion to dismiss. *See, e.g., United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000). Further, as this Court explained in its prior Order (Dkt. No. 268 at 12), “[N]either the FCA nor Rule 9(b) require the identification of individuals within a defendant corporation. The FCA imposes liability on “[a]ny *person* who” commits certain violations, , and for the purposes of the *FCA*, *person* includes corporations. 31 U.S.C. § 3729; *see Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 125 (2003).

b. Making or using false records or statements material to payment or approval of false claims under 31 U.S.C. § 3729(a)(1)(B)

To state a cause of action under 31 U.S.C. § 3729(a)(1)(B), Riedel must allege that BlueWave “knowingly ma[de], use[d], or cause [d] to be made or used, a false record or statement material to a false or fraudulent claim.” *See Triple Canopy*, 775 F.3d at 635 (citing

United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010)). Riedel's FAC clearly alleges that BlueWave *caused* false records material to false claims to be made and/or used. The creation of false records (*e.g.*, false Medicare forms) is the necessary, foreseeable, and obvious consequence of BlueWave's use of materials that highlighted the laboratories' no-balance billing practices to induce referrals from physicians. *See U.S. ex rel. DeCesare v. Americare In Home Nursing*, 757 F. Supp. 2d 573, 589 (E.D. Va. 2010) (outlining this traditional tort principle of proximate causation). Any record or statement that must be submitted to Medicare for reimbursement is material because it has "a natural tendency to influence, or be capable of influencing, the Government's decision to pay." *See Triple Canopy*, 775 F.3d at 634 (quoting 31 U.S.C. § 3729(b)(4)(internal quotation marks omitted)). The Riedel FAC has therefore sufficiently alleged that BlueWave caused the creation of false records that were material to false claims.

c. Retention of proceeds to which not entitled under 31 U.S.C. § 3729(a)(1)(G)

The retention of proceeds provision of the FCA (often referred to as the "reverse false claims" provision) imposes liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). In this context, an "obligation" is "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3).

Riedel asserts that the following facts are sufficient to allege a violation of the reverse false claims provision:

The Amended Complaint alleges BlueWave illegally obtained more than \$218 million in payments from HDL and Singulex in exchange [for] arranging the referral of business from physicians who received remuneration in the form of copay and deductible waivers and speaker fees. ¶¶ 77, 79. BlueWave used false statements and documents (see e.g. Exhibit 1 to Amended Complaint) to obtain these referrals and these payments from HDL and Singulex. The original source of those ill-gotten millions of dollars was largely the Medicare program. BlueWave knew these arrangements were illegal, and therefore knew its conduct had resulted in BlueWave obtaining money to which it was not entitled and which it was obligated to return to the government. BlueWave failed to do so, despite knowing of its obligation to do so.

(Dkt. No. 312 at 21.) Riedel has provided no legal support for the proposition that BlueWave had an obligation under 31 U.S.C. § 3729(a)(1)(G) to return funds to the government simply because it knew the funds were fraudulently obtained and that the government was the original source of the funds. The type of obligation contemplated under 31 U.S.C. § 3729(a)(1)(G) is, for example, the Medicaid program requirement that a provider return overpayments to the government within 60 days of when the overpayment is identified. *See* 42 U.S.C. § 1320a-7k(d)(2); *United States v. Compassionate Home Care Servs., Inc.*, No. 7:14-CV-113-D, 2017 WL 1030706, at *2 (E.D.N.C. Mar. 15, 2017). Under Plaintiff's interpretation "just about *any* traditional false statement or presentment action would give rise to a reverse false claim action; after all, presumably any false statement actionable under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money." *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014); *see also United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 338 (S.D.N.Y. 2004) ("And of course, if the conduct that gives rise to a traditional presentment or false statement action also

satisfies the demands of section 3729(a)(1)(G), then there would be nothing “reverse” about an action brought under that latter section of the FCA.”)

d. Conspiracy to commit an FCA violation under 31 U.S.C. § 3729(a)(1)(C)

To state a claim for conspiracy under 31 U.S.C. § 3729(a)(1)(C), the Riedel FAC must allege formation of an unlawful agreement between conspirators to get the Government to reimburse a false or fraudulent claim; (2) specific intent to defraud the Government and use the false record to achieve the conspiracy; and (3) at least one overt act in furtherance of the conspiracy. *DeCesare*, 757 F. Supp. 2d at 582.

Riedel’s FAC alleges that (1) BlueWave entered into agreements with both HDL and Singulex to violate the FCA by paying kickbacks to physicians to induce referrals for government-paid business (via co-payment and deductible waivers and speaker fees), and (2) BlueWave used this agreed-upon kickback scheme to market HDL and Singulex tests to physicians. (Dkt. No. 286 ¶¶ 42, 43, 73-79, 98, 99.) Riedel has adequately alleged that BlueWave entered an agreement with specific intent to defraud the government and completed an act (specifically, marketing to physicians) in furtherance of that conspiracy.³

BlueWave argues that any “purported conspiracy between BlueWave and HDL or between Singulex and BlueWave . . . fails due to the intracorporate immunity doctrine.” (Dkt. No. 293 at 198.) A conspiracy requires an agreement two or more persons, so the intracorporate conspiracy doctrine stands for the proposition that a corporation cannot conspire with its agents. *Buschi v. Kirven*, 775 F.2d 1240, 1251 (4th Cir. 1985). This court has already found that HDL

³ Plaintiff’s allegations are also sufficient to plead conspiracy as to conduct prior to May 20, 2009. For claims before May 20, 2009, Riedel must allege that BlueWave (1) “conspire[d] to defraud the Government by getting a false or fraudulent claim paid,” 31 U.S.C. § 3729(a)(3) (2000), and (2) “agreed to make use of the false record or statement to achieve this end.” *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008).

and BlueWave are separate entities. (Dkt. No. 268 at 15.) BlueWave has provided no support for its assertion that the intracorporate immunity doctrine applies or that BlueWave is part of the same corporation as either HDL or Singulex. Provided with no evidence to the contrary, this Court finds that the doctrine does not apply here.

Conclusion

For the foregoing reasons, BlueWave's motion to dismiss (Dkt. No. 293) is **GRANTED IN PART** and **DENIED IN PART**.

The motion to dismiss is **GRANTED** with regard to (1) Riedel's claims in connection with the P&H fees and Unnecessary Tests and (2) claims under 31 U.S.C. § 3729(a)(1)(G) (retention of proceeds to which not entitled, or reverse false claims).

The motion to dismiss is **DENIED** with regard to (1) the Speakers Bureau kickback scheme; (2) the waiver of co-payments/deductibles kickback scheme; (3) claims under 31 U.S.C. § 3729(a)(1)(B) (making or using false records or statements material to payment or approval of false claims); and (4) claims under 31 U.S.C. § 3729(a)(1)(C) (conspiracy to commit FCA violations).

AND IT IS SO ORDERED.



Richard M. Gergel
United States District Judge

March 23, 2017
Charleston, South Carolina